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IS/ISO/TS 22003 (2007): Food Safety Management systems - Requirements for bodies providing audit and certification of food safety management systems [FAD 15: Food Hygiene, Safety Management and Other Systems]



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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

खाद्य सुरक्षा प्रबंध पद्धतियाँ — खाद्य सुरक्षा प्रबंध पद्धतियों का
संपरीक्षण एवं प्रमाणन प्रदान करने वाले निकायों की अपेक्षाएँ

Indian Standard

**FOOD SAFETY MANAGEMENT SYSTEMS —
REQUIREMENTS FOR BODIES PROVIDING AUDIT
AND CERTIFICATION OF FOOD SAFETY
MANAGEMENT SYSTEMS**

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BUREAU OF INDIAN STANDARDS
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NATIONAL FOREWORD

This Indian Standard which is identical with ISO/TS 22003 : 2007 'Food safety management systems — Requirements for bodies providing audit and certification of food safety management systems' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Food Hygiene, Safety Management and Other Systems Sectional Committee and approval of the Food and Agriculture Division Council.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 19011 : 2002 Guidelines for quality and/or environmental management systems auditing	IS/ISO 19011 : 2002 Guidelines for quality and/or environmental management systems auditing	Identical
ISO 22000 : 2005 Food safety management systems — Requirements for any organization in the food chain	IS/ISO 22000 : 2005 Food safety management systems — Requirements for any organization in the food chain	do

The technical committee responsible for the preparation of this standard has reviewed the provisions of following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO/IEC 17000 : 2004	Conformity assessment — Vocabulary and general principles
ISO/IEC 17021 : 2006	Conformity assessment — Requirements for bodies providing audit and certification of management systems

Introduction

Certification of the food safety management system (FSMS) of an organization is one means of providing assurance that the organization has implemented a system for the management of food safety in line with its policy.

Requirements for FSMSs can originate from a number of sources, and this Technical Specification has been developed to assist in the certification of FSMSs that fulfil the requirements of ISO 22000, *Food safety management systems — Requirements for any organization in the food chain*. The contents of this Technical Specification may also be used to support certification of FSMSs that are based on other sets of specified FSMS requirements.

This Technical Specification is intended for use by bodies that carry out audit and certification of FSMSs. It gives generic requirements for such certification bodies performing audit and certification in the field of food safety management systems. Such bodies are referred to as certification bodies. This wording should not be an obstacle to the use of this Technical Specification by bodies with other designations that undertake activities covered by the scope of this document. Indeed, this Technical Specification should be usable by any body involved in the assessment of FSMSs.

Certification activities involve the audit of an organization's FSMS. The form of attestation of conformity of an organization's FSMS to a specific FSMS standard (for example ISO 22000) or other specified requirements is normally a certification document or a certificate.

It is for the organization being certified to develop its own management systems (including ISO 22000 FSMS, other sets of specified FSMS requirements, quality management systems, environmental management systems or occupational health and safety management systems) and, other than where relevant legislative requirements specify to the contrary, it is for the organization to decide how the various components of these will be arranged. The degree of integration between the various management system components will vary from organization to organization. It is therefore appropriate for certification bodies that operate in accordance with this Technical Specification to take into account the culture and practices of their clients with respect to the integration of their FSMSs within the wider organization.

Indian Standard

FOOD SAFETY MANAGEMENT SYSTEMS — REQUIREMENTS FOR BODIES PROVIDING AUDIT AND CERTIFICATION OF FOOD SAFETY MANAGEMENT SYSTEMS

1 Scope

This Technical Specification

- defines the rules applicable for the audit and certification of a food safety management system (FSMS) complying with the requirements given in ISO 22000 (or other sets of specified FSMS requirements), and
- provides the necessary information and confidence to customers about the way certification of their suppliers has been granted.

Certification of FSMSs (named "certification" in this Technical Specification) is a third-party conformity assessment activity (see ISO/IEC 17000:2004, 5.5). Bodies performing this activity are therefore third-party conformity assessment bodies (named "certification body/bodies" in this Technical Specification).

NOTE 1 Certification of an FSMS is sometimes also called "registration", and certification bodies are sometimes called "registrars".

NOTE 2 A certification body can be non-governmental or governmental (with or without regulatory authority).

NOTE 3 This Technical Specification is primarily intended to be used as a criteria document for the accreditation or peer assessment of certification bodies which seek to be recognized as being competent to certify that an FSMS complies with ISO 22000. It is also intended to be used as a criteria document by regulatory authorities and industry consortia which engage in direct recognition of certification bodies to certify that an FSMS complies with ISO 22000. Some of its requirements could also be found useful by any other parties involved in the conformity assessment of such certification bodies, and in the conformity assessment of any bodies that undertake to certify the compliance of FSMSs with criteria additional to or other than those in ISO 22000.

FSMS certification does not attest to the safety or fitness of the products of an organization within the food chain. However, ISO 22000 requires an organization to meet all applicable food-safety-related statutory and regulatory requirements through its management system.

It is important to note that certification of an FSMS according to ISO 22000 is a management system certification and not a product certification.

Other FSMS users can use the concepts and requirements of this Technical Specification provided that the requirements are adapted as necessary.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 19011:2002, *Guidelines for quality and/or environmental management systems auditing*

ISO 22000:2005, *Food safety management systems — Requirements for any organization in the food chain*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021:2006, *Conformity assessment — Requirements for bodies providing audit and certification of management systems*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC 17021, ISO 22000 and the following apply.

NOTE In this Technical Specification, the terms "product" and "service" are used separately, which is not in accordance with the definition of product given in ISO/IEC 17000.

3.1

hazard analysis and critical control point

HACCP

system which identifies, evaluates and controls hazards which are significant for food safety

NOTE Adapted from Reference [8].

3.2

food safety management system

FSMS

set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives, used to direct and control an organization with regard to food safety

NOTE See 3.2.1, 3.2.2 and 3.2.3 of ISO 9000:2005.

4 Principles

The principles given in Clause 4 of ISO/IEC 17021:2006 are the basis for the subsequent specific performance and descriptive requirements in this Technical Specification. This Technical Specification does not give specific requirements for all situations that can occur. These principles should be applied as guidance for the decisions that may need to be made for unanticipated situations. Principles are not requirements.

The term "management system" used in ISO/IEC 17021 shall be replaced by "food safety management system" in the context of this Technical Specification.

5 General requirements

5.1 General

All the requirements given in Clause 5 of ISO/IEC 17021:2006 apply.

5.2 Management of impartiality

The certification body and any part of the same legal entity shall not offer or provide hazard analysis consultancy, FSMS consultancy or management system consultancy.

The fact that the organization employing the auditor is known to have provided hazard analysis consultancy, FSMS consultancy or management system consultancy on the management system, within two years following the end of the consultancy, is likely to be considered as a high threat to impartiality.

The term "management system consultancy" mentioned in 5.2 of ISO/IEC 17021:2006 shall be replaced in the context of this Technical Specification by "hazard analysis consultancy, FSMS consultancy or management system consultancy".

6 Structural requirements

All the requirements given in Clause 6 of ISO/IEC 17021:2006 apply.

7 Resource requirements

7.1 Competence of management and personnel

All the requirements given in 7.1 of ISO/IEC 17021:2006 apply.

Additionally, the certification body shall have processes to ensure that personnel have appropriate knowledge relevant to the categories (see Annex A) in which it operates.

7.2 Personnel involved in the certification activities

7.2.1 General

7.2.1.1 All the requirements given in 7.2 of ISO/IEC 17021:2006 apply.

7.2.1.2 The certification body shall ensure that all personnel involved in the audit and certification activities possess the following personal attributes. The personnel shall be

- a) ethical (i.e. fair, truthful, sincere, honest and discreet),
- b) open-minded (i.e. willing to consider alternative ideas or points of view),
- c) diplomatic (i.e. tactful in dealing with people),
- d) observant (i.e. actively aware of physical surroundings and activities),
- e) perceptive (i.e. instinctively aware of and able to understand situations),
- f) versatile (i.e. adjust readily to different situations),
- g) tenacious (i.e. persistent, focused on achieving objectives),
- h) decisive (i.e. reach timely conclusions based on logical reasoning and analysis), and
- i) self-reliant (i.e. act and function independently while interacting effectively with others).

7.2.2 Personnel carrying out contract review

7.2.2.1 Education

The certification body shall ensure that personnel carrying out contract review have the knowledge corresponding to a secondary education.

7.2.2.2 Food safety training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in

- a) hazard analysis and critical control point (HACCP) principles, hazard assessment and hazard analysis,
- b) food safety management principles including prerequisite programmes (PRPs), and
- c) relevant FSMS standards (e.g. ISO 22000).

7.2.2.3 Audit training

The certification body shall ensure that personnel carrying out contract review have successfully completed training in audit processes based on the guidance given in ISO 19011.

NOTE It is not mandatory for personnel carrying out contract review to have or to maintain audit experience.

7.2.2.4 Competences

The certification body shall ensure that personnel carrying out contract review demonstrate the ability to apply knowledge and skills in the following areas:

- a) classification of applicants in food chain categories and sectors;
- b) assessment of applicant products, processes and practices;
- c) deployment of FSMS auditor competences and requirements;
- d) determination of audit time (see Annex B) and duration requirements;
- e) certification body's policies and procedures related to contract review.

7.2.3 Personnel granting certification

7.2.3.1 General

The certification body shall ensure that the personnel who take the decision on granting certification have the same education, food safety training, audit training and work experience as required for an auditor in one category (see Annex A).

NOTE It is not mandatory for personnel granting certification to have or to maintain audit experience.

7.2.3.2 Competences

The certification body shall ensure that personnel granting certification demonstrate the ability to apply knowledge and skills in the following areas:

- a) current principles of HACCP;
- b) understanding of PRPs;
- c) identification of food safety hazards;
- d) implementation and management of food safety hazards, critical control points (CCPs) and the ability to assess the effectiveness of selected control measures;
- e) corrections and corrective actions to be taken with regards to food safety matters;

- f) assessment of potential food safety hazards linked to the food supply chain;
- g) laws and regulations relevant to food safety, in order to be able to conduct an effective audit of the FSMS;
- h) products, processes and practices;
- i) relevant food safety management system requirements;
- j) relevant standards;
- k) assessment and review of an audit report for accuracy and completeness;
- l) assessment and review of the effectiveness of corrective actions;
- m) the certification process.

7.2.4 Auditors

7.2.4.1 Education

The certification body shall ensure that auditors have the knowledge corresponding to a post-secondary education that includes general microbiology and general chemistry.

The certification body shall also ensure that auditors have the knowledge corresponding to a post-secondary education that includes courses in the food chain industry category in which they conduct FSMS audits.

EXAMPLES

- a) For the food industry (Categories C, D, E, F, G and H in Table A.1): food microbiology, food processing fundamentals and food chemistry including food analysis.
- b) For farming (plants) (Category B in Table A.1): crop production.
- c) For farming (animals) (Categories A and F in Table A.1): animal production.
- d) For packaging/food machine/engineering industry (Categories I to M in Table A.1): science/engineering courses related to the discipline.

7.2.4.2 Food safety training

The certification body shall ensure that auditors have successfully completed training in

- a) HACCP principles, hazard assessment and hazard analysis, and
- b) food safety management principles including PRPs.

The training course(s) should be recognized by the industry (and its stakeholders) as being appropriate and relevant. The approval or certification of the training courses by an independent body with the relevant expertise can provide some assurance that the course meets specified criteria.

7.2.4.3 Audit training

The certification body shall ensure that auditors have successfully completed training in

- a) audit techniques based on ISO 19011, and
- b) relevant FSMS standards (e.g. ISO 22000).

7.2.4.4 Work experience

For a first qualification of an auditor in one or more categories, the certification body shall ensure that the auditor has a minimum of five years of full-time work experience in the food-chain-related industry, including at least two years of work in quality assurance or food safety functions within food production or manufacturing, retailing, inspection or enforcement, or the equivalent.

The number of years of total work experience may be reduced by one year if the auditor has completed appropriate post-secondary education.

7.2.4.5 Audit experience

For a first qualification, the certification body shall ensure that within the last three years the auditor has performed at least twelve FSMS audit days in at least four organizations under the leadership of a qualified auditor.

NOTE FSMS audit days include audit days dealing with ISO 9001 in the food industry or other FSMS audits.

For extension to a new category, the certification body shall demonstrate that the auditor has the required competences through relevant education as required in 7.2.4.1, food-safety-related training in the new category, and either

- six months of work experience in the new category, or
- four FSMS audits under the supervision of a qualified auditor in the new category.

For maintaining the qualification of the auditor, the certification body shall ensure that auditors have performed either

- a minimum of five external audits per year, including at least two FSMS audits, or
- a minimum of four FSMS on-site external audits or ten FSMS audit days per year.

7.2.4.6 Competences

7.2.4.6.1 The competences of auditors shall be recorded [see 5.5 c) of ISO 19011:2002] for each category and sector (see Annex A). The certification body shall provide evidence of a successful evaluation.

7.2.4.6.2 The certification body shall ensure that auditors demonstrate the ability to apply knowledge and skills in the following areas.

- a) Audit principles, procedures and techniques: to enable the auditor to apply those appropriate to different audits and to ensure that audits are conducted in a consistent and systematic manner. An auditor shall be able
 - to apply audit principles, procedures and techniques,
 - to plan and organize the work effectively,
 - to conduct the audit within the agreed time schedule,
 - to prioritize and focus on matters of significance,
 - to collect information through effective interviewing, listening, observing and reviewing documents, records and data,
 - to understand the appropriateness and consequences of using sampling techniques for auditing,
 - to verify the accuracy of collected information,

- to confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions,
 - to assess those factors that can affect the reliability of the audit findings and conclusions,
 - to use work documents to record audit activities,
 - to prepare audit reports,
 - to maintain the confidentiality and security of information, and
 - to communicate effectively, either through personal linguistic skills or through an interpreter.
- b) **Management system and reference documents:** to enable the auditor to comprehend the scope of the audit and apply audit criteria. Knowledge and skills in this area shall cover
- the application of management systems to different organizations,
 - interaction between the components of the management system,
 - food safety management system standards, applicable procedures or other management system documents used as audit criteria,
 - recognizing differences between, and the priority of, the reference documents,
 - application of the reference documents to different audit situations, and
 - information systems and technology for authorization, security, distribution and control of documents, data and records.
- c) **Organizational situations:** to enable the auditor to comprehend the organization's operational context. Knowledge and skills in this area shall cover
- organizational size, structure, functions and relationships,
 - general business processes and related terminology, and
 - cultural and social customs of the auditee.
- d) **Applicable laws, regulations and other requirements relevant to the discipline:** to enable the auditor to work within, and be aware of, the requirements that apply to the organization being audited. Knowledge and skills in this area shall cover
- local, regional and national codes, laws and regulations,
 - contracts and agreements,
 - international treaties and conventions, and
 - other requirements to which the organization subscribes.

7.2.4.6.3 The certification body shall ensure that auditors demonstrate the ability to apply terminology, knowledge and skills in the following food safety specific areas:

- a) current principles of HACCP;
- b) relevant PRPs for the considered category(ies) (see Annex A);
- c) identification of food safety hazards;
- d) methodologies used for determination, implementation and management of control measures (PRPs, operational PRPs and CCPs) and the ability to assess the effectiveness of selected control measures;

- e) corrections and corrective actions to be taken with regards to food safety matters;
- f) assessment of potential food safety hazards linked to the food supply chain;
- g) evaluation of the relevance of the applicable PRPs, including establishing or selecting an appropriate evaluation method or guide for these PRPs for the category(ies) considered (see Annex A);
- h) laws and regulations relevant to food safety in order to be able to conduct an effective audit of the FSMS;
- i) products, processes and practices of the specific sector(s) (see Annex A);
- j) relevant food safety management system requirements;
- k) relevant food safety standards.

7.2.5 Technical experts

7.2.5.1 Education

The certification body shall ensure that technical experts have the knowledge corresponding to a post-secondary education in the food chain industry sector being audited, in the processes being audited or in the food safety hazards applicable to the sector.

7.2.5.2 Work experience

The certification body shall ensure that technical experts have work experience in their technical area.

7.2.5.3 Competences

The certification body shall ensure that technical experts demonstrate the ability to provide expertise in their technical area.

7.2.6 Selection of the audit team

The certification body shall ensure that the FSMS audit team have competences in the application of PRPs and HACCP in the specific sector required by the audit (see Annex A).

7.3 Use of individual external auditors and external technical experts

All the requirements given in 7.3 of ISO/IEC 17021:2006 apply.

7.4 Personnel records

All the requirements given in 7.4 of ISO/IEC 17021:2006 apply.

7.5 Outsourcing

All the requirements given in 7.5 of ISO/IEC 17021:2006 apply.

8 Information requirements

All the requirements given in Clause 8 of ISO/IEC 17021:2006 apply.

The certification documents shall identify in detail what activity is certified, referring to sectors (see Annex A).

9 Process requirements

9.1 General requirements

9.1.1 The certification body shall precisely define the scope of certification in terms of levels of the food chain (e.g. primary production, food processing, packaging material production), category(ies) and sectors according to Annex A. The certification body shall not exclude part of the processes, sectors, products or services from the scope of certification when those processes, sectors, products or services have an influence on the food safety of the end products.

9.1.2 The certification body shall have a process for choosing the audit day, time and season so that the audit team has the opportunity of auditing the organization operating on a representative number of product lines, categories and sectors covered by the scope.

9.1.3 All the requirements given in 9.1.1 to 9.1.3 of ISO/IEC 17021:2006 apply.

9.1.4 The certification body shall have documented procedures for determining audit time, and for each client the certification body shall determine the time needed to plan and accomplish a complete and effective audit of the client's FSMS. The audit time determined by the certification body, and the justification for the determination, shall be recorded. In determining the audit time, the certification body should consider Annex B and shall consider, among other things, the following aspects:

- a) requirements of the relevant FSMS standard;
- b) size and complexity of the organization;
- c) technological and regulatory context;
- d) any outsourcing of any activities included in the scope of the FSMS;
- e) results of any prior audits;
- f) number of sites and multi-site considerations.

9.1.5 For multi-site organizations, the requirements given in 9.1.5.1 and 9.5.1.3 apply.

9.1.5.1 Where the certification body is certifying a multi-site organization under one certificate, the following conditions apply:

- a) all sites are of the same activity and are located within the same country;
- b) all sites are operating under one centrally controlled and administered FSMS as defined in Clause 4 of ISO 22000:2005, or equivalent for other FSMSs;
- c) an internal audit has been conducted on each site within the three years prior to certification;
- d) following certification, an internal audit shall be carried out on each site within the certification period;
- e) the internal audits of all sites shall comply with ISO 22000 or equivalent;
- f) audit findings of the individual sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

9.1.5.2 The use of multi-site sampling is only possible for organizations with more than 20 sites and only for categories A, B, G, H and J (see Table A.1). This applies both to the initial certification and to surveillance audits.

9.1.5.3 Where the certification body offers multi-site certification, the certification body shall utilize a sampling programme to ensure an effective audit of the FSMS where

- a) the sampling for more than 20 sites shall be at the ratio of 1 site per 5 sites with a minimum of 20. All sites shall be randomly selected and, after the audit, no sampled sites may be nonconforming (i.e. not meeting certification thresholds for ISO 22000),
- b) evaluation of the audit findings of the sampled sites shall be deemed equivalent to the internal audit findings of the same sites of the organization,
- c) at least annually, an audit of the central FSMS shall be performed,
- d) at least annually, surveillance audits shall be performed on the sampled sites, and
- e) audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Table 1 gives examples of the number of sites to audit when sampling is used.

Table 1 — Examples of the number of sites to be audited when multi-site sampling is used

	Total number of sites								
	x between 1 and 20	21	22	23	24	25	26	27	28
Number of sites above 20	0	1	2	3	4	5	6	7	8
Additional number of sites to audit	0	1	1	1	1	1	2	2	2
Number of sites to be audited	x	21	21	21	21	21	22	22	22

9.1.6 All the requirements given in 9.1.6 to 9.1.9 of ISO/IEC 17021:2006 apply.

9.1.7 The certification body shall provide a written report for each audit. The report shall be based on relevant guidance provided in ISO 19011. The audit team may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the audit report shall be maintained by the certification body.

The report shall include references to PRPs used by the organization, HACCP methodology used, comments on the HACCP team, and other issues relevant to the FSMS.

9.1.8 All the requirements given in 9.1.11 to 9.1.15 of ISO/IEC 17021:2006 apply.

9.2 Initial audit and certification

9.2.1 Application

All the requirements given in 9.2.1 of ISO/IEC 17021:2006 apply.

The certification body shall require the applicant organization to provide detailed information concerning process lines, HACCP studies and the number of shifts.

9.2.2 Application review

All the requirements given in 9.2.2 of ISO/IEC 17021:2006 apply.

9.2.3 Initial certification audit

The initial certification audit of an FSMS shall be conducted in two stages: stage 1 and stage 2.

9.2.3.1 Stage 1 audits

9.2.3.1.1 All the requirements given in 9.2.3.1.1 of ISO/IEC 17021:2006 apply.

Where an organization has implemented an externally developed combination of control measures, the stage 1 audit shall review the documentation included in the FSMS to determine if the combination of control measures is suitable for the organization, was developed in compliance with the requirements of ISO 22000, and is kept up to date.

The availability of relevant authorizations should be checked when collecting the information regarding the compliance to regulatory aspects.

9.2.3.1.2 The objectives of the stage 1 audit are to provide a focus for planning the stage 2 audit by gaining an understanding of the FSMS in the context of the organization's food safety hazard identification, analysis, HACCP plan and PRPs, policy and objectives, and, in particular, the organization's state of preparedness for audit by reviewing the extent to which

- a) the organization has identified PRPs that are appropriate to the business (e.g. regulatory and statutory requirements),
- b) the FSMS includes adequate processes and methods for the identification and assessment of the organization's food safety hazards, and subsequent selection and categorization of control measures (combinations),
- c) food safety legislation is in place for the relevant sector(s) of the organization,
- d) the FSMS is designed to achieve the organization's food safety policy,
- e) the FSMS implementation programme justifies proceeding to the audit (stage 2),
- f) the validation, verification and improvement programmes conform to the requirements of the FSMS standard,
- g) the FSMS documents and arrangements are in place to communicate internally and with relevant suppliers, customers and interested parties, and
- h) additional documentation needs to be reviewed and/or what knowledge needs to be obtained in advance.

9.2.3.1.3 For FSMS, the stage 1 audit shall be carried out at the client's premises in order to achieve the objectives stated above.

9.2.3.1.4 All the requirements given in 9.2.3.1.2 of ISO/IEC 17021:2006 apply.

The client shall be informed that the results of the stage 1 audit may lead to postponement or cancellation of the stage 2 audit.

9.2.3.1.5 Any part of the FSMS that is audited during the stage 1 audit and determined to be fully implemented, effective and in conformity with requirements, may not need to be re-audited during the stage 2 audit. However, the certification body shall ensure that the already audited parts of the FSMS continue to conform to the certification requirements. In this case, the stage 2 audit report shall include these findings and shall clearly state that conformity has been established during the stage 1 audit.

9.2.3.1.6 All the requirements given in 9.2.3.1.3 of ISO/IEC 17021:2006 apply.

The interval between stage 1 and stage 2 audits is reasonably expected to be not longer than 6 months. The stage 1 audit should be repeated if a longer interval is needed.

9.2.3.2 Stage 2 audit

All the requirements given in 9.2.3.2 of ISO/IEC 17021:2006 apply.

9.2.4 Initial certification audit conclusions

All the requirements given in 9.2.4 of ISO/IEC 17021:2006 apply.

9.2.5 Information for granting initial certification

All the requirements given in 9.2.5 of ISO/IEC 17021:2006 apply.

9.3 Surveillance activities

All the requirements given in 9.3 of ISO/IEC 17021:2006 apply.

9.4 Recertification

All the requirements given in 9.4 of ISO/IEC 17021:2006 apply.

9.5 Special audits

All the requirements given in 9.5 of ISO/IEC 17021:2006 apply.

9.6 Suspending, withdrawing or reducing the scope of certification

All the requirements given in 9.6 of ISO/IEC 17021:2006 apply.

9.7 Appeals

All the requirements given in 9.7 of ISO/IEC 17021:2006 apply.

9.8 Complaints

All the requirements given in 9.8 of ISO/IEC 17021:2006 apply.

9.9 Records of applicants and clients

All the requirements given in 9.9 of ISO/IEC 17021:2006 apply.

10 Management system requirements for certification bodies

All the requirements given in Clause 10 of ISO/IEC 17021:2006 apply.

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Annex A (normative)

Classification of food chain categories

The certification body shall use Table A.1

- a) to define the scope that it undertakes,
- b) to identify if any technical qualification of its auditors is necessary for that particular category or sector, and
- c) to select a suitably qualified audit team.

The examples given in Table A.1 are not exhaustive but are only an indication of relevant topics.

The scope of one specific client organization may cover more than one category.

Table A.1 — Food chain categories

Category codes	Categories	Examples of sectors
A	Farming 1 (Animals)	animals; fish; egg production; milk production; beekeeping; fishing; hunting; trapping
B	Farming 2 (Plants)	fruits; vegetables; grain; spices; horticultural products
C	Processing 1 (Perishable animal products) including all activities after farming, e.g. slaughtering	meat, poultry, eggs, dairy and fish products
D	Processing 2 (Perishable vegetal products)	fresh fruits and fresh juices; preserved fruits; fresh vegetables; preserved vegetables
E	Processing 3 (Products with long shelf life at ambient temperature)	canned products; biscuits; snacks; oil; drinking water; beverages; pasta; flour; sugar; salt
F	Feed production	animal feed; fish feed
G	Catering	hotels; restaurants
H	Distribution	retail outlets; shops; wholesalers
I	Services	water supply; cleaning; sewage; waste disposal; development of product, process and equipment; veterinary services
J	Transport and storage	transport and storage
K	Equipment manufacturing	process equipment; vending machines
L	(Bio)chemical manufacturing	additives; vitamins; pesticides; drugs; fertilizers; cleaning agents; biocultures
M	Packaging material manufacturing	packaging material

Annex B **(informative)**

Minimum audit time

B.1 General

In determining the audit time needed for each site, as required in 9.1.4, the certification body should consider the minimum on-site duration for initial certification given in Table B.1.

The minimum time includes stage 1 and stage 2 of the initial certification audit (see 9.2.3) but does not include the time for preparation of the audit nor for writing the audit report.

The minimum audit time is established for the audit of an FSMS which includes only one HACCP study. A HACCP study corresponds to a hazard analysis for a family of products/services with similar hazards and similar production technology and, where relevant, similar storage technology.

The minimum surveillance audit time should be one-third of the initial certification audit time, with a minimum of 0,5 audit days. The minimum renewal time should be two-thirds of the initial certification audit time, with a minimum of 0,5 audit days.

Where there is no relevant certified management system in place, additional time should be added for the audit. To be considered relevant, a management system certificate should cover the scope of food safety for the relevant product/service.

The number of employees should be expressed as the number of full-time equivalent employees (FTEs).

Certain categories are subject to multi-site sampling (see 9.1.5.2) and this may be taken into account when calculating the audit time.

Other factors may necessitate increasing the minimum audit time (e.g. number of product types, number of product lines, product development, number of CCPs, number of operational PRPs, building area, infrastructure, in-house laboratory testing, need for a translator).

B.2 Calculation of minimum initial certification audit time

B.2.1 Minimum audit time for single site, Ts:

$$T_s = (D + H + MS + FTE)$$

where

D is the basis on-site audit time;

H is the audit days for additional HACCP studies;

MS is the audit days for absence of relevant management system;

FTE is the audit days per number of employees.

B.2.2 Minimum audit time for each additional site, Tm:

$$T_m = T_s \times 50/100$$

Table B.1 — Minimum initial certification audit time

Category (see Annex A)	D Basic on-site audit time (in audit days)	H For each additional HACCP study (in audit days)	MS Absence of certified relevant management system (in audit days)	FTE Number of employees (in audit days)	For each additional site visited
A	0,75	0,25	0,25	1 to 19 = 0 20 to 49 = 0,5 50 to 79 = 1,0 80 to 199 = 1,5 200 to 499 = 2,0 500 to 899 = 2,5 900 to 1 299 = 3,0 1 300 to 1 699 = 3,5 1 700 to 2 999 = 4,0 3 000 to 5 000 = 4,5 > 5 000 = 5,0	50 % of minimum on-site audit time
B	0,75	0,25			
C	1,50	0,50			
D	1,00	0,50			
E	1,50	0,50			
F	1,50	0,50			
G	1,00	0,50			
H	1,00	0,50			
I	1,00	0,25			
J	1,00	0,25			
K	1,00	0,25			
L	1,50	0,50			
M	1,00	0,25			

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